DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

IMMUNALYSIS CORPORATION
JOSEPH GINETE
REGULATORY AFFAIRS SPECIALIST
829 TOWNE CENTER DRIVE
POMONA CA 91767

February 6, 2015

Re: K143500
Trade/Device Name: Immunalysis Amphetamine Urine Enzyme Immunoassay,
Immunalysis Amphetamine Urine Calibrator,
Immunalysis Amphetamine Urine Control Set
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ, DLJ, LAS
Dated: December 9, 2014
Received: December 10, 2014

Dear Mr. Joseph Ginete:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143500

Device Name
Immunalysis Amphetamine Urine Enzyme Immunoassay, Immunalysis Amphetamine Urine Calibrators, Immunalysis Amphetamine Urine Control Set

Indications for Use *(Describe)*
The Immunalysis Amphetamine Urine Enzyme Immunoassay Kit is a homogeneous enzyme immunoassay with dual cutoffs of 500 ng/mL and 1000 ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of Amphetamine in human urine with automated clinical chemistry analyzers. This assay is calibrated against Amphetamine. This in-vitro device is for prescription use only.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC-MS or permitting laboratories to establish quality control procedures.

The Immunalysis Amphetamine Urine Enzyme Immunoassay Kit provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC-MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Immunalysis Amphetamine Urine Controls: The Immunalysis Amphetamine Urine Controls are used as control materials in Immunalysis Amphetamine Urine Enzyme Immunoassay.

Immunalysis Amphetamine Urine Calibrators: The Immunalysis Amphetamine Urine Calibrators are used as calibrators in the Immunalysis Amphetamine Urine Enzyme Immunoassay. for the qualitative and semi-quantitative determination of Amphetamine in urine on automated clinical chemistry analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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IMMUNALYSIS

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

A. Contact Information

1. Manufacturer: Immunalysis Corporation
2. Contact Name: Joseph Ginete
3. Contact Title: Regulatory Affairs Specialist
4. Address: 829 Towne Center Drive Pomona, CA 91767
5. Phone: (909) 482-0840
6. Fax: (909) 482-0850
7. Email: jginete@immunalysis.com
8. Summary prepared on: January 27, 2015

B. Device Information

1. Trade Name: Immunalysis Amphetamine Urine Enzyme Immunoassay
   Immunalysis Amphetamine Urine Controls
   Immunalysis Amphetamine Urine Calibrators
2. Common Name: Immunalysis Amphetamine Urine Enzyme Immunoassay
   Immunalysis Amphetamine Urine Controls
   Immunalysis Amphetamine Urine Calibrators
3. Device Classification: II
4. Regulation Number: CFR 862.3100 Enzyme Immunoassay, Amphetamine
   CFR 862.3200 Calibrators, Drug Specific
   CFR 862.3280 Drug Specific Control Materials
5. Panel: Toxicology(91)
6. Product Code: DKZ
   DLJ
   LAS

C. Legally Marketed Device to Which We are Claiming Equivalence (807.92(A)(3))

1. Predicate Device: VITROS® Chemistry Products AMPH Reagent
   VITROS® Chemistry Products Calibrator Kit 26
   VITROS® Chemistry Products FS Calibrator 1
   VITROS® Chemistry Products DAT Performance Verifiers I, II, III, IV and V
2. Predicate Company: Ortho-Clinical Diagnostics, Inc
3. Predicate K Number: K062077

D. Device Description

The assay consists of antibody/ substrate reagent and enzyme conjugate reagent. The antibody/ substrate reagent includes monoclonal antibodies to Amphetamine, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in Tris buffer with Sodium Azide as a preservative. The enzyme conjugate reagent includes amphetamine derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with Sodium Azide as a preservative. Calibrators and controls are sold separately. Reagents are liquid, ready to use

The amphetamine calibrator and controls consist of dual cutoff calibrators at 500ng/mL and 1000ng/mL, a control set containing a LOW control at 375ng/mL and a HIGH control at 625ng/mL for the 500ng/mL cutoff and a LOW control at 750ng/mL and HIGH control at 1250ng/mL for the 1000ng/mL cutoff, and a calibrator set containing a negative calibrator, a Level 1 calibrator at 500ng/mL, a Level 2 calibrator at 1000ng/mL, a Level 3 calibrator at 1500ng/mL, and a Level 4 calibrator at 2000ng/mL.

E. Intended Use

The Immunalysis Amphetamine Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with dual cutoffs of 500ng/mL and 1000ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of Amphetamine in human urine with automated clinical chemistry analyzers. This assay is calibrated against Amphetamine. This in-vitro device is for prescription use only.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC-MS or permitting laboratories to establish quality control procedures.

The Immunalysis Amphetamine Urine Enzyme Immunoassay Kit provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrometry (GC-MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Immunalysis Amphetamine Urine Controls: The Immunalysis Amphetamine Urine Controls are used as control materials in Imunalysis Amphetamine Urine Enzyme Immunoassay.

Immunalysis Amphetamine Urine Calibrators: The Immunalysis Amphetamine Urine Calibrators are used as calibrators in the Immunalysis Amphetamine Urine Enzyme Immunoassay for the qualitative and semi-quantitative determination of Amphetamine in urine on automated clinical chemistry analyzers

F. Comparison of the new device with the predicate device

Item	**Amphetamine Assay K062077**	**Immunalysis Amphetamine Urine EIA**
Intended Use	For the qualitative and semi-quantitative determination of the presence of amphetamine in human urine at a cutoff of 500ng/mL and 1000ng/mL	For the qualitative and semi-quantitative determination of the presence of amphetamine in human urine at a cutoff of 500ng/mL and 1000ng/mL
Type of Product	Analytical Reagents	Analytical Reagents
Measured Analytes	Amphetamine	Amphetamine
Test Matrix	Urine	Urine
Cutoff Levels	500ng/mL and 1000ng/mL of Amphetamine	500ng/mL and 1000ng/mL of Amphetamine
Test System	Homogeneous Enzyme Immunoassay	Homogenous Enzyme Immunoassay
Materials	Liquid Ready-to-Use Two Reagent Assay (R1 and R2)	Antibody/Substrate Reagents and Enzyme Labeled Conjugate
Mass Spectroscopy Confirmation	Required for preliminary positive analytical results	Required for preliminary positive analytical results
Antibody	Mouse Monoclonal antibodies to Amphetamine and Methamphetamine	Monoclonal antibody to Amphetamine
Storage	2 – 8°C until expiration date	2 – 8°C until expiration date
Calibrator Form	Liquid	Liquid
Calibrator Levels	Six (6) Levels	Two (2) Levels and Five (5) Levels
Control Levels	Five (5) Levels	Four (4) Levels

G. The following laboratory performance studies were performed to determine substantial equivalence of the Immunalysis Amphetamine Urine Enzyme Immunoassay to the predicate

1. Precision/Cutoff Characterization – Study was performed for 20 days, 2 runs per day in duplicate (N=80) on concentration of ±25%, ±50%, ±75%, and ±100% of the cutoff. The study verified that the cutoff serves as a boundary between a negative and positive interpretation of a qualitative result. In addition, it also verified that product performance relative to the ability of the device to produce the same value during repeated measurements. The instruments used for this was Beckman Coulter AU 400e.

a. The following is a summary table of the Qualitative Analysis for the 500ng/mL cutoff test data results.

Table 1 - Qualitative Analysis (for 500ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
125	-75%	80	80 Negative
250	-50%	80	80 Negative
375	-25%	80	80 Negative
500	Cutoff	80	48 Negative / 32 Positive
625	+25%	80	80 Positive
750	+50%	80	80 Positive
875	+75%	80	80 Positive
1000	+100%	80	80 Positive

b. The following is a summary table of the Qualitative Analysis for the 1000ng/mL cutoff test data results.

Table 2 - Qualitative Analysis (for 1000 ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
250	-75%	80	80 Negative
500	-50%	80	80 Negative
750	-25%	80	80 Negative
1000	Cutoff	80	47 Negative / 33 Positive
1250	+25%	80	80 Positive
1500	+50%	80	80 Positive
1750	+75%	80	80 Positive
2000	+100%	80	80 Positive

c. The following is a summary table of the Semi-Quantitative Analysis for the 500ng/mL cutoff test data results.

Table 3 - Semi-Quantitative Analysis (for 500ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
125	-75%	80	80 Negative
250	-50%	80	80 Negative
375	-25%	80	80 Negative
500	Cutoff	80	31 Negative / 49 Positive
625	+25%	80	80 Positive
750	+50%	80	80 Positive
875	+75%	80	80 Positive
1000	+100%	80	80 Positive

d. The following is a summary table of the Semi-Quantitative Analysis for the 1000ng/mL cutoff test data results.

Table 4 - Semi-Quantitative Analysis (for 1000ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
250	-75%	80	80 Negative
500	-50%	80	80 Negative
750	-25%	80	80 Negative
1000	Cutoff	80	36 Negative / 44 Positive
1250	+25%	80	80 Positive
1500	+50%	80	80 Positive
1750	+75%	80	80 Positive
2000	+100%	80	80 Positive

2. Specificity and Cross-Reactivity – Structurally similar compounds were spiked into drug free urine at levels that will yield a result that is equivalent to the cutoffs. The study verified assay performance relative to the ability of the device to exclusively determine certain drugs. The instrument used for this test was a Beckman Coulter AU 400e.

a. The qualitative result summary table for the 500ng/mL cutoff is outlined below:

Table 5 - Structurally Related Compounds (for 500 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
(+) Amphetamine	500	POS	100.0
(-) Amphetamine	100,000	POS	0.5
(±) Amphetamine	1,300	POS	38.5
MDA	1,500	POS	33.3
PMA	2,000	POS	25.0
Tyramine	100,000	POS	0.5
MDMA	500,000	POS	0.1
MDEA	100,000	POS	0.5
Phenylpropanolamine	500,000	POS	0.1
Phentermine	1,000,000	POS	0.05
(+) Methamphetamine	1,000,000	POS	0.05
(-) Methamphetamine	1,000,000	NEG	N.D.
(+) Ephedrine	1,000,000	NEG	N.D.
(-) Ephedrine	1,000,000	NEG	N.D.
(+) Pseudoephedrine	1,000,000	NEG	N.D.
(-) Pseudoephedrine	1,000,000	NEG	N.D.
Phenylephrine	1,000,000	NEG	N.D.
Diphenylhydramine	1,000,000	NEG	N.D.
Fenfluramine	1,000,000	NEG	N.D.

N.D. = < 0.05%

b. The qualitative result summary table for the 1000ng/mL cutoff is outlined below:

Table 6 - Structurally Related Compounds (for 1000 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
(+) Amphetamine	1000	POS	100.0
(-) Amphetamine	200,000	POS	0.5
(±) Amphetamine	2,500	POS	40.0
MDA	2,000	POS	50.0
PMA	4,000	POS	25.0
Tyramine	400,000	POS	0.3
MDMA	1,000,000	NEG	N.D.
MDEA	400,000	POS	0.3
Phenylpropanolamine	1,000,000	NEG	N.D.
Phentermine	1,000,000	NEG	N.D.
(+) Methamphetamine	1,000,000	NEG	N.D.
(-) Methamphetamine	1,000,000	NEG	N.D.
(+) Ephedrine	1,000,000	NEG	N.D.
(-) Ephedrine	1,000,000	NEG	N.D.
(+) Pseudoephedrine	1,000,000	NEG	N.D.
(-) Pseudoephedrine	1,000,000	NEG	N.D.
Phenylephrine	1,000,000	NEG	N.D.
Diphenylhydramine	1,000,000	NEG	N.D.
Fenfluramine	1,000,000	NEG	N.D.

N.D. = < 0.05%

c. The semi-quantitative result summary table for the 500ng/mL cutoff is outlined below:

Table 7 - Structurally Related Compounds (for 500ng/mL cutoff) – Semi-Quantitative		
Compound	Concentration Tested (ng/mL)	Cross-Reactivity (%)
(+) Amphetamine	500	100.0
(-) Amphetamine	100,000	0.5
(±) Amphetamine	1,300	38.5
MDA	1,500	33.3
PMA	2,000	25.0
Tyramine	100,000	0.5
MDMA	500,000	0.1
MDEA	100,000	0.5
Phenylpropanolamine	500,000	0.1
Phentermine	1,000,000	0.05
(+) Methamphetamine	1,000,000	0.05
(-) Methamphetamine	1,000,000	N.D.
(+) Ephedrine	1,000,000	N.D.
(-) Ephedrine	1,000,000	N.D.
(+) Pseudoephedrine	1,000,000	N.D.
(-) Pseudoephedrine	1,000,000	N.D.

Table 7 - Structurally Related Compounds (for 500ng/mL cutoff) – Semi-Quantitative		
Compound	Concentration Tested (ng/mL)	Cross-Reactivity (%)
Phenylephrine	1,000,000	N.D.
Diphenylhydramine	1,000,000	N.D.
Fenfluramine	1,000,000	N.D.

N.D. = < 0.05%

d. The semi-quantitative result summary table for the 1000ng/mL cutoff is outlined below:

Table 8 - Structurally Related Compounds (for 1000ng/mL cutoff) – Semi-Quantitative		
Compound	Concentration Tested (ng/mL)	Cross-Reactivity (%)
(+) Amphetamine	1000	100.0
(-) Amphetamine	200,000	0.5
(±) Amphetamine	2,500	40.0
MDA	2,000	50.0
PMA	4,000	25.0
Tyramine	400,000	0.3
MDMA	1,000,000	N.D.
MDEA	400,000	0.3
Phenylpropanolamine	1,000,000	N.D.
Phentermine	1,000,000	N.D.
(+) Methamphetamine	1,000,000	N.D.
(-) Methamphetamine	1,000,000	N.D.
(+) Ephedrine	1,000,000	N.D.
(-) Ephedrine	1,000,000	N.D.
(+) Pseudoephedrine	1,000,000	N.D.
(-) Pseudoephedrine	1,000,000	N.D.
Phenylephrine	1,000,000	N.D.
Diphenylhydramine	1,000,000	N.D.
Fenfluramine	1,000,000	N.D.

N.D. = < 0.05%

3. Interference – Structurally non-similar compounds, endogenous compounds, the effect of pH and the effect of specific gravity was evaluated by spiking the potential interferent into drug free urine containing the target analyte at ±25% of the cutoff. All potential interferents analyzed verified that assay performance is unaffected by externally ingested compounds or an internally existing physiological condition. The instrument used for this test was a Beckman Coulter AU 400e.
    a. The following is a summary table of the structurally non-similar compounds for the 500ng/mL cutoff :

Table 9 - Structurally Non-Similar Compounds (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Result	Interference?	Result	Interference?
4-Bromo- 2 ,5 , Dimethoxyphenethylamine	100,000	Negative	No	Positive	No
6-Acetylmorphine	100,000	Negative	No	Positive	No
7-Aminoclonazepam	100,000	Negative	No	Positive	No

Table 9 - **Structurally Non-Similar Compounds** (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Result	Interference?	Result	Interference?
Acetaminophen	500,000	Negative	No	Positive	No
Acetylsalicyclic Acid	500,000	Negative	No	Positive	No
Alprazolam	100,000	Negative	No	Positive	No
Amitriptyline	100,000	Negative	No	Positive	No
Amobarbital	100,000	Negative	No	Positive	No
Benzoylecgonine	500,000	Negative	No	Positive	No
Benzylpiperazine	100,000	Negative	No	Positive	No
Bromazepam	100,000	Negative	No	Positive	No
Buprenorphine	100,000	Negative	No	Positive	No
Bupropion	100,000	Negative	No	Positive	No
Butabarbital	100,000	Negative	No	Positive	No
Caffeine	100,000	Negative	No	Positive	No
Carbamazepine	100,000	Negative	No	Positive	No
Chlorpromazine	100,000	Negative	No	Positive	No
Chrlordiazepoxide	100,000	Negative	No	Positive	No
cis-Tramadol	100,000	Negative	No	Positive	No
Clobazam	100,000	Negative	No	Positive	No
Clomipramine	100,000	Negative	No	Positive	No
Clonazepam	100,000	Negative	No	Positive	No
Cocaine	100,000	Negative	No	Positive	No
Codeine	100,000	Negative	No	Positive	No
Cyclobenzaprine	100,000	Negative	No	Positive	No
N-Demethyltapentadol	100,000	Negative	No	Positive	No
Delta-9-THC	100,000	Negative	No	Positive	No
Desipramine	100,000	Negative	No	Positive	No
Dextromethorphan	100,000	Negative	No	Positive	No
Diazepam	100,000	Negative	No	Positive	No
Dihydrocodeine	100,000	Negative	No	Positive	No
Doxepin	100,000	Negative	No	Positive	No
EDDP	100,000	Negative	No	Positive	No
Ethyl β-D-glucuronide	100,000	Negative	No	Positive	No
Ethylmorphine	100,000	Negative	No	Positive	No
Flunitrazepam	100,000	Negative	No	Positive	No
Fluoxetine	100,000	Negative	No	Positive	No
Flurazepam	100,000	Negative	No	Positive	No
Heroin	100,000	Negative	No	Positive	No
Hexobarbital	100,000	Negative	No	Positive	No
Hydrocodone	100,000	Negative	No	Positive	No
Hydromorphone	100,000	Negative	No	Positive	No
11-hydroxy-delta-9-THC	100,000	Negative	No	Positive	No
Ibuprofen	100,000	Negative	No	Positive	No
Imipramine	100,000	Negative	No	Positive	No
Ketamine	100,000	Negative	No	Positive	No
Levorphanol Tartrate	100,000	Negative	No	Positive	No

Table 9 - **Structurally Non-Similar Compounds** (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Result	Interference?	Result	Interference?
Lidocaine	100,000	Negative	No	Positive	No
Lorazepam	100,000	Negative	No	Positive	No
LSD	100,000	Negative	No	Positive	No
Maprotiline	100,000	Negative	No	Positive	No
Meperidine	100,000	Negative	No	Positive	No
Meprobamate	100,000	Negative	No	Positive	No
Methadone	500,000	Negative	No	Positive	No
Methaquolone	100,000	Negative	No	Positive	No
Methylphenidate	100,000	Negative	No	Positive	No
Morphine	100,000	Negative	No	Positive	No
Morphine-6 -glucuronide	100,000	Negative	No	Positive	No
Nalorphine	100,000	Negative	No	Positive	No
Naloxone	100,000	Negative	No	Positive	No
Naltrexone	100,000	Negative	No	Positive	No
Nitrazepam	100,000	Negative	No	Positive	No
Norbuprenorphine	100,000	Negative	No	Positive	No
Norcodeine	100,000	Negative	No	Positive	No
Nordiazepam	100,000	Negative	No	Positive	No
Normorphine	100,000	Negative	No	Positive	No
Norpropoxyphene	100,000	Negative	No	Positive	No
Nortriptyline	100,000	Negative	No	Positive	No
Oxazepam	100,000	Negative	No	Positive	No
Oxycodone	100,000	Negative	No	Positive	No
Oxymorphone	100,000	Negative	No	Positive	No
PCP	100,000	Negative	No	Positive	No
Pentazocine	100,000	Negative	No	Positive	No
Pentobarbital	100,000	Negative	No	Positive	No
Phenobarbital	100,000	Negative	No	Positive	No
Phenytoin	100,000	Negative	No	Positive	No
Prazepam	100,000	Negative	No	Positive	No
Propranolol	100,000	Negative	No	Positive	No
Protriptyline	100,000	Negative	No	Positive	No
Ranitidine	100,000	Negative	No	Positive	No
Ritalinic Acid	100,000	Negative	No	Positive	No
Secobarbial	100,000	Negative	No	Positive	No
Sufentanil Citrate	100,000	Negative	No	Positive	No
Temazepam	100,000	Negative	No	Positive	No
11-nor-9 carboxy THC	100,000	Negative	No	Positive	No
Thioridazine	100,000	Negative	No	Positive	No
Triazolam	100,000	Negative	No	Positive	No
Trifluoromethylphenyl-piperazine	100,000	Negative	No	Positive	No
Trimipramine	100,000	Negative	No	Positive	No
Venlafaxine	100,000	Negative	No	Positive	No

b. The following is a summary table of the structurally non-similar compounds for the 1,000ng/mL cutoff:

Table 10 - Structurally Non-Similar Compounds (for 1000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (750ng/mL)**		**+25% Cutoff (1250ng/mL)**	
		Result	Interference?	Result	Interference?
4-Bromo- 2 ,5 , Dimethoxyphenethylamine	100,000	Negative	No	Positive	No
6-Acetylmorphine	100,000	Negative	No	Positive	No
7-Aminoclonazepam	100,000	Negative	No	Positive	No
Acetaminophen	500,000	Negative	No	Positive	No
Acetylsalicyclic Acid	500,000	Negative	No	Positive	No
Alprazolam	100,000	Negative	No	Positive	No
Amitriptyline	100,000	Negative	No	Positive	No
Amobarbital	100,000	Negative	No	Positive	No
Benzoylecgonine	500,000	Negative	No	Positive	No
Benzylpiperazine	100,000	Negative	No	Positive	No
Bromazepam	100,000	Negative	No	Positive	No
Buprenorphine	100,000	Negative	No	Positive	No
Bupropion	100,000	Negative	No	Positive	No
Butabarbital	100,000	Negative	No	Positive	No
Caffeine	100,000	Negative	No	Positive	No
Carbamazepine	100,000	Negative	No	Positive	No
Chlorpromazine	100,000	Negative	No	Positive	No
Chrlordiazepoxide	100,000	Negative	No	Positive	No
cis-Tramadol	100,000	Negative	No	Positive	No
Clobazam	100,000	Negative	No	Positive	No
Clomipramine	100,000	Negative	No	Positive	No
Clonazepam	100,000	Negative	No	Positive	No
Cocaine	100,000	Negative	No	Positive	No
Codeine	100,000	Negative	No	Positive	No
Cyclobenzaprine	100,000	Negative	No	Positive	No
N-Demethyltapentadol	100,000	Negative	No	Positive	No
Delta-9-THC	100,000	Negative	No	Positive	No
Desipramine	100,000	Negative	No	Positive	No
Dextromethorphan	100,000	Negative	No	Positive	No
Diazepam	100,000	Negative	No	Positive	No
Dihydrocodeine	100,000	Negative	No	Positive	No
Doxepin	100,000	Negative	No	Positive	No
EDDP	100,000	Negative	No	Positive	No
Ethyl β-D-glucuronide	100,000	Negative	No	Positive	No
Ethylmorphine	100,000	Negative	No	Positive	No
Flunitrazepam	100,000	Negative	No	Positive	No
Fluoxetine	100,000	Negative	No	Positive	No
Flurazepam	100,000	Negative	No	Positive	No
Heroin	100,000	Negative	No	Positive	No
Hexobarbital	100,000	Negative	No	Positive	No

Table 10 - **Structurally Non-Similar Compounds** (for 1000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (750ng/mL)**		**+25% Cutoff (1250ng/mL)**	
		Result	Interference?	Result	Interference?
Hydrocodone	100,000	Negative	No	Positive	No
Hydromorphone	100,000	Negative	No	Positive	No
11-hydroxy-delta-9-THC	100,000	Negative	No	Positive	No
Ibuprofen	100,000	Negative	No	Positive	No
Imipramine	100,000	Negative	No	Positive	No
Ketamine	100,000	Negative	No	Positive	No
Levorphanol Tartrate	100,000	Negative	No	Positive	No
Lidocaine	100,000	Negative	No	Positive	No
Lorazepam	100,000	Negative	No	Positive	No
LSD	100,000	Negative	No	Positive	No
Maprotiline	100,000	Negative	No	Positive	No
Meperidine	100,000	Negative	No	Positive	No
Meprobamate	100,000	Negative	No	Positive	No
Methadone	500,000	Negative	No	Positive	No
Methaquolone	100,000	Negative	No	Positive	No
Methylphenidate	100,000	Negative	No	Positive	No
Morphine	100,000	Negative	No	Positive	No
Morphine-6 -glucuronide	100,000	Negative	No	Positive	No
Nalorphine	100,000	Negative	No	Positive	No
Naloxone	100,000	Negative	No	Positive	No
Naltrexone	100,000	Negative	No	Positive	No
Nitrazepam	100,000	Negative	No	Positive	No
Norbuprenorphine	100,000	Negative	No	Positive	No
Norcodeine	100,000	Negative	No	Positive	No
Nordiazepam	100,000	Negative	No	Positive	No
Normorphine	100,000	Negative	No	Positive	No
Norpropoxyphene	100,000	Negative	No	Positive	No
Nortriptyline	100,000	Negative	No	Positive	No
Oxazepam	100,000	Negative	No	Positive	No
Oxycodone	100,000	Negative	No	Positive	No
Oxymorphone	100,000	Negative	No	Positive	No
PCP	100,000	Negative	No	Positive	No
Pentazocine	100,000	Negative	No	Positive	No
Pentobarbital	100,000	Negative	No	Positive	No
Phenobarbital	100,000	Negative	No	Positive	No
Phenytoin	100,000	Negative	No	Positive	No
Prazepam	100,000	Negative	No	Positive	No
Propranolol	100,000	Negative	No	Positive	No
Protriptyline	100,000	Negative	No	Positive	No
Ranitidine	100,000	Negative	No	Positive	No
Ritalinic Acid	100,000	Negative	No	Positive	No
Secobarbial	100,000	Negative	No	Positive	No
Sufentanil Citrate	100,000	Negative	No	Positive	No
Temazepam	100,000	Negative	No	Positive	No

Table 10 - Structurally Non-Similar Compounds (for 1000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
11-nor-9 carboxy THC	100,000	Negative	No	Positive	No
Thioridazine	100,000	Negative	No	Positive	No
Triazolam	100,000	Negative	No	Positive	No
Trifluoromethylphenyl-piperazine	100,000	Negative	No	Positive	No
Trimipramine	100,000	Negative	No	Positive	No
Venlafaxine	100,000	Negative	No	Positive	No

c. The following is a summary table of the endogenous compounds results for the 500ng/mL cutoff:

Table 11 - Endogenous Compounds (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (375ng/mL)		+25% Cutoff (625ng/mL)	
		Result	Interference?	Result	Interference?
Acetone	1.0 g/dL	Negative	No	Positive	No
Ascorbic Acid	1.5 g/dL	Negative	No	Positive	No
Bilirubin	0.002 g/dL	Negative	No	Positive	No
Creatinine	0.5 g/dL	Negative	No	Positive	No
Ethanol	1.0 g/dL	Negative	No	Positive	No
Galactose	0.01 g/dL	Negative	No	Positive	No
γ-Globulin	0.5 g/dL	Negative	No	Positive	No
Glucose	2.0 g/dL	Negative	No	Positive	No
Hemoglobin	0.150 g/dL	Negative	No	Positive	No
Human Serum Albumin	0.5 g/dL	Negative	No	Positive	No
Oxalic Acid	0.1 g/dL	Negative	No	Positive	No
Riboflavin	0.0075 g/dL	Negative	No	Positive	No
Sodium Azide	1% w/v	Negative	No	Positive	No
Sodium Chloride	6.0 g/dL	Negative	No	Positive	No
Sodium Flouride	1% w/v	Negative	No	Positive	No
Urea	6.0 g/dL	Negative	No	Positive	No

d. The following is a summary table of the endogenous compounds results for the 1,000ng/mL cutoff:

Table 12 - Endogenous Compounds (for 1000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
Acetone	1.0 g/dL	Negative	No	Positive	No
Ascorbic Acid	1.5 g/dL	Negative	No	Positive	No
Bilirubin	0.002 g/dL	Negative	No	Positive	No
Creatinine	0.5 g/dL	Negative	No	Positive	No
Ethanol	1.0 g/dL	Negative	No	Positive	No
Galactose	0.01 g/dL	Negative	No	Positive	No
γ-Globulin	0.5 g/dL	Negative	No	Positive	No
Glucose	2.0 g/dL	Negative	No	Positive	No
Hemoglobin	0.150 g/dL	Negative	No	Positive	No

Table 12 - Endogenous Compounds (for 1000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
Human Serum Albumin	0.5 g/dL	Negative	No	Positive	No
Oxalic Acid	0.1 g/dL	Negative	No	Positive	No
Riboflavin	0.0075 g/dL	Negative	No	Positive	No
Sodium Azide	1% w/v	Negative	No	Positive	No
Sodium Chloride	6.0 g/dL	Negative	No	Positive	No
Sodium Flouride	1% w/v	Negative	No	Positive	No
Urea	6.0 g/dL	Negative	No	Positive	No

e. The following is a summary table of Boric Acid for the 500ng/mL cutoff results:

Table 13 – Boric Acid (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (375ng/mL)		+25% Cutoff (625ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	Negative	No	Positive	No

f. The following is a summary table of the Boric Acid for the 1,000ng/mL cutoff results:

Table 14 – Boric Acid (for 1000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	Negative	No	Positive	No

g. The following is a summary table of the effect of pH results for the 500ng/mL cutoff:

Table 15 - Effect of pH (for 500ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (375ng/mL)		+25% Cutoff (625ng/mL)	
		Result	Interference?	Result	Interference?
pH	3.0	Negative	No	Positive	No
pH	4.0	Negative	No	Positive	No
pH	5.0	Negative	No	Positive	No
pH	6.0	Negative	No	Positive	No
pH	7.0	Negative	No	Positive	No
pH	8.0	Negative	No	Positive	No
pH	9.0	Negative	No	Positive	No
pH	10.0	Negative	No	Positive	No
pH	11.0	Negative	No	Positive	No

h. The following is a summary table of the effect of pH results for the 1,000ng/mL cutoff:

Table 16 - Effect of pH (for 1000ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
pH	3.0	Negative	No	Positive	No

Table 16 - Effect of pH (for 1000ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (750ng/mL)**		**+25% Cutoff (1250ng/mL)**	
		Result	Interference?	Result	Interference?
pH	4.0	Negative	No	Positive	No
pH	5.0	Negative	No	Positive	No
pH	6.0	Negative	No	Positive	No
pH	7.0	Negative	No	Positive	No
pH	8.0	Negative	No	Positive	No
pH	9.0	Negative	No	Positive	No
pH	10.0	Negative	No	Positive	No
pH	11.0	Negative	No	Positive	No

i. The following is a summary table of the effect of specific gravity results for 500ng/mL cutoff:

Table 17 - Effect of Specific Gravity (for 500ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Result	Interference?	Result	Interference?
Specific Gravity	1.000	Negative	No	Positive	No
Specific Gravity	1.002	Negative	No	Positive	No
Specific Gravity	1.005	Negative	No	Positive	No
Specific Gravity	1.010	Negative	No	Positive	No
Specific Gravity	1.015	Negative	No	Positive	No
Specific Gravity	1.020	Negative	No	Positive	No
Specific Gravity	1.025	Negative	No	Positive	No
Specific Gravity	1.030	Negative	No	Positive	No

j. The following is a summery table of the effect of specific gravity results for 1,000ng/mL cutoff:

Table 18 - Effect of Specific Gravity (for 1000ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (750ng/mL)**		**+25% Cutoff (1250ng/mL)**	
		Result	Interference?	Result	Interference?
Specific Gravity	1.000	Negative	No	Positive	No
Specific Gravity	1.002	Negative	No	Positive	No
Specific Gravity	1.005	Negative	No	Positive	No
Specific Gravity	1.010	Negative	No	Positive	No
Specific Gravity	1.015	Negative	No	Positive	No
Specific Gravity	1.020	Negative	No	Positive	No
Specific Gravity	1.025	Negative	No	Positive	No
Specific Gravity	1.030	Negative	No	Positive	No

4. Linearity/ Recovery – A drug free urine pool was spiked with high concentration of the target analyte as a high value specimen. Additional pools were made by serially diluting the high value specimen. The study verified assay linearity in the semi-quantitative mode. The instrument used for this test was a Beckman Coulter AU 400e.
    a. The following is a summary table of the linearity/recovery:

Table 19 - Linearity/ Recovery		
Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
200	152.3	76.2
400	367.5	91.9
500	504.4	100.9
600	614.4	102.4
800	856.5	107.1
1000	1026.9	102.7
1200	1171.4	97.6
1400	1357.1	96.9
1600	1461.1	91.3
1800	1714.0	95.2
2000	2046.5	102.3
2200	2256.4	102.6

5. Method Comparison – Unaltered, anonymous and discarded clinical urine samples obtained from clinical testing laboratories were analyzed with the test device. The study verified that the product performance can be verified by Mass Spectrometry. The instrument used for this test was a Beckman Coulter AU 400e and an Agilent 6430 Liquid Chromatography Tandem Mass Spectrometry.
    a. The following is a comparison table of qualitative assay performance for the 500ng/mL cutoff:

Table 20 - Method Comparison (for 500ng/mL cutoff) - Qualitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	0
	(-)	0	40

    b. The following is a summary table of qualitative assay performance for the 500ng/mL cutoff:

Table 21 - Assay Performance verified by LC/MS – 500ng/mL Cutoff					
Type	Amphetamine Concentration				Agreement (%)
	< 250ng/mL	250 ~ 499 ng/mL	500 ~ 750 ng/mL	> 750 ng/mL	
Qualitative/ Positive	0	0	4	36	100
Qualitative/ Negative	36	4	0	0	100

c. The following is a comparison table of qualitative assay performance for the 1,000ng/mL cutoff:

Table 22 - Method Comparison (for 1000ng/mL cutoff) - Qualitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	0
	(-)	1	40

d. The following is a summary table of qualitative assay performance for the 1,000ng/mL

Table 23 - Assay Performance verified by LC/MS – 1000ng/mL Cutoff					
Type	Amphetamine Concentration				Agreement (%)
	< 500ng/mL	500 ~ 999 ng/mL	1000 ~ 1500 ng/mL	> 1500 ng/mL	
Qualitative/ Positive	0	0	4	36	100
Qualitative/ Negative	34	6	1	0	98

e. The following is a summary table of qualitative discordant results for the 1000ng/mL cutoff

Table 24 - Discordant Result Summary – 1000ng/mL Cutoff – Qualitative			
Sample ID	In-House ID	Qualitative Results 1000ng/mL Cutoff	LC/MS Confirmation
		Test Device	Amphetamine
395246ZA	**16558**	**Negative**	**1173ng/mL**

f. The following is a comparison table of semi-quantitative assay performance for the 500ng/mL cutoff:

Table 25 - Method Comparison (for 500ng/mL cutoff) – Semi-Quantitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	0
	(-)	0	40

g. The following is a summary table of semi-quantitative assay performance for the 500ng/mL cutoff:

Table 26 - Assay Performance verified by LC/MS – 500ng/mL Cutoff					
Type	Amphetamine Concentration				Agreement (%)
	< 250ng/mL	250 ~ 499 ng/mL	500 ~ 750 ng/mL	> 750 ng/mL	
Semi-Quantitative/ Positive	0	0	4	36	100
Semi-Quantitative / Negative	36	4	0	0	100

h. The following is a comparison table of semi-quantitative assay performance for the 1,000ng/mL cutoff:

Table 27 - Method Comparison (for 1000ng/mL cutoff) – Semi-Quantitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	0
	(-)	1	40

i. The following is a summary table of semi-quantitative assay performance for the 1,000ng/mL cutoff:

Table 28 - Assay Performance verified by LC/MS – 1000ng/mL Cutoff					
Type	Amphetamine Concentration				Agreement (%)
	< 500ng/mL	500 ~ 999 ng/mL	1000 ~ 1500 ng/mL	> 1500 ng/mL	
Semi-Quantitative/ Positive	0	0	4	36	100
Semi-Quantitative / Negative	34	6	1	0	98

j. The following is a summary table of semi-quantitative discordant results for the 1000ng/mL cutoff

Table 29 - Discordant Result Summary – 1000ng/mL Cutoff – Semi-Quantitative				
Sample ID	In-House ID	Semi-Quantitative Results 1000ng/mL Cutoff		LC/MS Confirmation
		Value	Result	Amphetamine
395246ZA	**16558**	**620.6**	**Negative**	**1173ng/mL**

6. Stability –
   a. A closed accelerated stability study was performed on reagents, calibrators and controls at 25ºC to establish the initial expiration dating. The stability study supported an initial expiration date of 1 year for reagents. This stability study supported an initial expiration date of 12 months for calibrators and controls. The instrument used for this test was a Beckman Coulter AU 400e. Real time stability studies are ongoing.
   b. An open/on-board stability study was performed on reagents to establish expiration dating when reagents are opened and stored on board the instrument at 2ºC to 8ºC. The stability study supported an initial open vial expiration date of 28 days. The instrument used for this test was Beckman Coulter AU 400e.
7. Calibrator and Control Traceability – all components of the calibrator and controls have been traced to a commercially available standard solution
8. Calibrator and Control Stability – An open accelerated stability study was performed at 25ºC to establish the initial open vial expiration dating. The stability study supported an initial open vial expiration date of 6 months. The instrument used for this test was a Beckman Coulter AU 400e. All calibrator levels (500, 1,000, 1,500, and 2,000ng/mL) and control levels (375, 625, 750, 1,250ng/mL) were within specifications for Day 0, 8, 16, 32, and 40. This accelerated stability study was performed to establish initial expiration dating. Real time stability studies are ongoing.
9. Calibrator and Control Value Assignment – calibrators and controls are manufactured and are tested by mass spectrometry. If any of the analytes are out of the acceptable range, then the calibrator and control is adjusted and re-tested. Values are assigned to the calibrator and controls once the mass spectrometry results are within the acceptable ranges.

H. Conclusion

The information provided in this pre-market notification demonstrates that the Immunalysis Amphetamine Urine Enzyme Immunoassay is substantially equivalent to the legally marketed predicate device for its general intended use.